Summary of the
Proficiency Testing Committee Meeting
February 3, 1997

The National Environmental Laboratory Accreditation Conference (NELAC) Proficiency Testing (PT) Committee met from 10:30 a.m. to noon and from 1 to 2:50 p.m. Eastern Standard Time on Monday, February 3, 1997. The meeting was led by Ms. Andrea M. Jirka, chair, U.S. Environmental Protection Agency (USEPA). A list of action items is given in Attachment A. A list of Committee members/invited guests is given in Attachment B. A copy of the session agenda is given in Attachment C.

INTRODUCTION

The purpose of the meeting was to continue to review the fourth revision of Chapter 2, "Proficiency Testing Program." All chapter sections and subsections were reviewed. The following items were addressed:

- Introduction of Committee members,
- Overview presentation of Chapter 2, and
- Review of Chapter 2 sections and subsections**.**

REVIEW OF CHAPTER 2 SECTIONS AND SUBSECTIONS

2.1 -- Overview

It was noted that there was a need for a clear relationship between the PT score and the system audit. In reply, the Committee stated that it has not yet dealt with this issue. There was concern that the last two sentences add nothing to the section. There was no strong consensus to take action on this item.

2.1.1 -- Expectations

It was proposed that this section be retitled "Purpose." The Committee agreed to address this issue, and the contributor offered to provide appropriate rewording.

2.1.2 -- Practical Goals

It was suggested that this section be retitled "Goals of the Standards." It was noted that this section does not address the overall importance of PT samples to the accreditation process. The PT program provides a mechanism for comparison of laboratory performance on a national scale, and the section wording should reflect this concept. Item (b) was suggested to read "similar to" rather than "as close to." Item (b) calls for test samples to be similar to real-world samples. A question was raised about whether this would exclude the use of whole-volume samples. This matter is addressed in Appendix B. Discussion was heard about the relative merits of whole-volume and ampule PT samples. It was suggested that item (e) be added; this new item would state that PT samples for a given analyte should be of similar difficulty regardless of their source.

2.1.3 -- Scope

The issue of evaluation by "field of testing" versus method was raised. Further discussion was deferred until the joint meeting with the Program Policy and Structure Committee on Tuesday.

2.1.4 -- Fields of Testing
A contributor stated that Section 2.1.4 requires more detail. For example, it should describe issues such as concentration levels, types of analytes, and so on. The question of testing based on method/analyte, on program/method/analyte, and on program/analyte was raised again and will be discussed at Tuesday's meeting.

2.2 Major PT Participants
A question of whether the standard-setting authority is the National Environmental Laboratory Accreditation Program (NELAP) or NELAC was raised. The Committee will check for the appropriate use of these terms throughout the chapter. There is confusion in Figure 1 regarding the appearance of NELAP in the same box with "Standard-Setting Authority." A request was made for a better definition of "Oversight Body." Because laboratories may deal directly with PT sample providers, it was suggested that a two-way arrow be used between the "Providers" and "Laboratories" boxes in Figure 1. A contributor suggested that the term "participant" be better defined. The Committee agreed to consider this issue.

2.2.1 -- Standard-Setting Authority
The roles of NELAC versus NELAP were again raised. It was noted that the document does not clearly state that NELAP sets the data acceptance criteria. In response, the Committee stated that NELAP is the USEPA program with overall responsibility for the entire program and that NELAP works through NELAC, which has responsibility to develop standards. The Committee will work to clarify this issue in the next draft of the document.

2.2.2 -- PT Study Providers
No comments were received on this section.

2.2.3 -- Provider Oversight Body
A discussion developed about the nature of the information to be included in the NELAC database. If historical PT results are to be included in the database, should those results be on a pass/fail basis or on a numerical score basis? While accrediting authorities only need pass/fail scores, numerical scores might indicate problems with samples from particular PT providers. One of the issues is the amount and type of negative information that can be retained in a database. Placement of such data in the national database may raise legal issues. The feasibility/affordability of including large amounts of detailed data in the database was questioned.

2.2.4 -- Laboratories
A question was raised about whether laboratories would report their PT testing results by hard copy or electronically. This issue has not been addressed by the Committee.

2.2.5 -- Accrediting Authorities
It was noted that this section is redundant with material presented in Chapters 1 and 6. This section does not indicate recognition of the primacy of some programs. Concern was raised that wording in the section might disagree with that contained in Chapter 4, "Program Policy and Structure." There was concern that reciprocity was not reflected satisfactorily in this section.

2.3 -- Requirements for PT Providers and Studies
It was suggested that the last two sentences of this section be eliminated. Also, someone asked what "approved" means in this context; is a PT provider "approved" or "accredited"? The Committee will consider both of these matters.

It was noted that the material presented in Sections 2.3.1 through 2.3.6 are presented in greater detail in Appendix A. It was suggested that these sections be eliminated because the reader might assume that the body of the text was complete in itself. The Committee responded that its intention was to present a skeleton of the issues covered in these sections.

2.3.1 -- On-Site Audit of PT Providers
A contributor asked whether performance of an on-site audit on an annual basis is firmly established. Could such audits occur semiannually? The Committee responded that the frequency of audits is not firmly established. Details in the appendices are easily updated without having to modify chapter sections. A contributor noted that extensive use of appendices is inconsistent with other chapters in the standards; other chapters include details within the body of the text. This inconsistency will be addressed through coordination with other committees.

2.3.2 -- Sample Requirements and Design
Someone asked whether the wording of this section dictates the use of full-volume samples. The Committee responded that this was not the case. Someone asked for clarification on the meaning of "reuse." In response, it was stated that particular sample materials may not be relabeled and reused for further testing. Someone suggested that the reference to "reuse" be deleted.

2.3.2.1 -- Sample Analyses
No comments were received on this section.

2.3.2.2 -- Provider Sample Testing
No comments were received on this section.

2.3.3 -- PT Study Data Analysis
No comments were received on this section.

2.3.3.1 -- Data Set Size Requirements
No comments were received on this section.

2.3.3.2 -- Data Acceptance Criteria
It was suggested that data acceptance criteria be presented in detail in this section of the chapter. The Committee responded that this will be covered in Appendix C. It was noted that a laboratory serving as a PT sample provider and also as an analytical service laboratory may create a conflict of interest. This issue has yet to be addressed.

2.3.4 -- Generation of Study Reports
Someone asked about the origin of the 21-day requirement for completion of the report by the PT provider. The Committee responded that this number was reached through consensus.

2.3.5 -- Provider Ethics
A contributor noted that the chapter on quality systems indicates that records should be retained for 10 years, whereas this subsection states retention should be 5 years. This issue needs clarification.

2.3.6 -- Final NELAP Approval
It was suggested that Sections 2.3.5 and 2.3.6 be combined.

2.3.7 -- Disapproval of PT Study Providers
Several questions were raised about this section. One was about the responsibility of the provider to notify laboratories that it is no longer an approved provider. The second was the existence of provisions to allow for reapproval after approval has been revoked.

2.3.8 -- NELAP Listing of PT Study Providers
No comments were received on this section.

2.4 -- Laboratory Enrollment in Proficiency Testing Program(s)
No comments were received on this section.

2.4.1 -- Required Level of Participation
There was significant discussion about a laboratory being accredited for individual analytes versus for groups or suites of analytes. It was pointed out that many laboratories perform analyses for clients that include a very limited number of analytes. In other cases, laboratories perform analyses for clients that include all the analytes normally listed in a program-defined class or category of compounds. The Committee supports accreditation for individual analytes as a means of dealing with both of these situations. Under this approach, a laboratory that has been accredited for a subset of a given category of analytes and seeks accreditation for another subset of the same category will have to go through the normal process of accreditation for this second subset.

It was noted that the requirement for a laboratory to participate in two PT studies per year is inconsistent with wording addressing this issue in other sections. The Committee will review this inconsistency.

2.4.2 -- Requesting Accreditation
No comments were received on this section.

2.4.3 -- Reporting Results
Someone asked whether a laboratory could select any PT provider. It was noted that States have the authority to designate providers. NELAC cannot limit State authority. A laboratory must be accredited in the State in which it is located. This issue is also being addressed by the Accreditation Authority Committee.

2.5 -- Requirements for Laboratory Testing of PT Study Samples
There was extensive discussion about the requirement for PT results to be reported no later than 30 calendar days from the date of sample receipt. Some contributors indicated that certain types of analyses typically take much longer than 30 days; the need for more time arises sometimes from attempts to balance heavy workloads. Other contributors argued that 30 days should be more than sufficient and that most analyte holding times are less than 30 days. It was further stated that PT samples should be analyzed with the same frequency as equivalent real-world samples. A straw poll was taken regarding the 30-day requirement. Twenty-seven of 35 respondents indicated satisfaction with the current 30-day requirement. Six preferred a longer time frame, and 2 preferred variable time frames dependent on specific analytes. It was recognized that radiochemical and microbiological samples pose their own specific stability/handling problems.

There was extensive discussion on the way PT samples are analyzed relative to real-world samples. It was generally acknowledged that PT samples are analyzed more carefully and

thoroughly than day-to-day real-world samples. Some States require that a laboratory sign an affidavit or attest to the fact that PT samples are treated no differently than real-world samples. While difficult to enforce 100% of the time, the standard should strongly state the importance of analyzing PT samples and real-world samples using equivalent procedures.

Concern was raised about whether "should" in line 7 of this section should be replaced with "must." A straw poll indicated no strong consensus about whether the word "should" should remain, be replaced with "must," or be reworded otherwise.

2.5.1 -- Restrictions on Exchanging Information
There was strong opposition to the use of the word "may." It was recommended that this be changed to "shall." Section 2.5.1(b) needs clarification in regard to "may not knowingly receive." Suggested alternative wording included "prior to receiving."

2.5.1.1 -- Consequences of Unauthorized Communication
A discrepancy was recognized between the wording "one year" in line 5 with information in Chapter 4. This inconsistency will be resolved by the Committee. It was suggested that information regarding the suspension of a laboratory be included in the national database, perhaps to even include the reason for the loss of accreditation. The legalities of including such information should be investigated.

2.5.2 -- Maintenance of Records
It was noted that the issue of record maintenance is well-covered in Chapter 5, "Quality Systems," and Chapter 6, "Accrediting Authority." The Committee will resolve any redundancies and/or discrepancies, including the time required for maintenance of records.

2.6 -- Evaluation of Proficiency Testing Results
A question was raised about whether this is a "Federal" program or solely a USEPA program. The response was that proficiency testing is a USEPA program. A contributor asked whether specific criteria for evaluating testing results should be placed in the body of Chapter 2. It was noted that this will be addressed in Appendix C, but the general basis for such evaluation is to be included in Chapter 2.

2.6.1 -- Scoring of Laboratory PT Study Results
No comments were received on this section.

2.7 -- PT Criteria for Laboratory Accreditation
Concern was raised about whether a laboratory could maintain its accredited status by alternately passing and failing PT rounds. Two failures out of three attempts would result in a loss of accreditation.

2.7.1 -- Accreditation Categories
It was noted that the term "accreditation categories" should be written as "results categories."

2.7.2 -- Initial and Continuing Accreditation
A contributor noted that having to pass two PT rounds before accreditation presents a hardship, because the total time involved may be as much as 2 ½ months. Another contributor noted that this is actually a speedier process than that which exists in his State, where accreditation may take 6 months or longer. The second to the last sentence in Section 2.7.2 needs clarification.

A contributor asked whether laboratory accreditation could be grandfathered. The response was that the States will deal with this issue.

2.7.3 -- Supplemental Studies
No comments were received on this section.

2.7.4 -- Failed Studies and Corrective Action
Discussion was heard concerning the appropriateness of references in this section to accreditation and accrediting authority. A contributor asked why loss of accreditation would be at the discretion of the accrediting authority, when the standards for loss of accreditation are established by NELAC. In response to this question, it was proposed that the last sentence terminate after the word "standard" in line 6. There was consensus for this action.

2.7.5 -- Second Failed Study
No comments were received on this section.

2.7.6 -- Reapplication after Second Failed Study
A contributor asked why any requirements are being placed on a laboratory that has lost accreditation. It was noted that laboratories may often lose accreditation for only one analyte or for a few in a larger group for which they are accredited. Requiring corrective action is a way to assist a laboratory in overcoming its problems and regaining accreditation.

PRESENTATION OF NIST REFERENCE MATERIAL SUPPORT PROGRAM

Ms. Reenie Parris presented an overview of the reference materials program at the National Institute of Standards and Technology (NIST). This included an explanation of the NIST Traceable Reference Materials support program, in which NIST certifies reference materials prepared by commercial suppliers. She also described how NIST might play a role in NELAP. NIST could work with commercial suppliers of PT materials to develop program protocols, assist the suppliers in producing high-quality materials, and provide a well-defined quality assurance (QA) infrastructure.

NEXT MEETING

The next meeting is scheduled for 9 a.m. EST on Tuesday, February 4, 1997. This will be a joint meeting with the NELAC Program Policy and Structure Committee.

Attachment A

ACTION ITEMS
Proficiency Testing Committee
February 3, 1997

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Item No.	Action	Date Completed
1	The Committee will obtain overheads of the NIST presentation from Ms. Reenie Parris.	
2	The Committee will review and consider all suggestions for modification of the chapter.	
3	Program/analyte versus program/method/analyte bases for accreditation should be scheduled for discussion during the February 4, 1997, joint meeting with the Program Policy and Structure Committee.	
4	The Committee will review the chapter for the appropriate use of the terms “NELAC” and “NELAP.”	
5	The Committee, in conjunction with the efforts of the Coordination Committee, will review the chapter for consistency with all other chapters of the NELAC standards.	

Attachment B

LIST OF PARTICIPANTS
Proficiency Testing Committee
February 3, 1997

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Attachment C

AGENDA
Proficiency Testing Committee
February 3, 1997

9:00 a.m. Eastern Standard Time

1. Introduction of Committee members.

2. Overview Presentation of Chapter 2.

3. Review of Chapter 2 Sections and Subsections.

1:00 p.m. Eastern Standard Time

1. Presentation of NIST Reference Materials Support Program.

2. Completion of review of Chapter 2 Sections and Subsections.